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IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* [UNDER SEAL],	)	
Plaintiff,	)	
v.	)	Civil Action No. 19-1220
[UNDER SEAL],	)	
Defendant.	)	

FILED UNDER SEAL

FILED
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CLERK U.S. DISTRICT COURT
WEST. DIST. OF PENNSYLVANIA

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* **DIANA ZALDONIS** **and** **DIANA ZALDONIS** 4007 Fredricksburg Court Export, PA 15632 **Plaintiffs,** **v.** **UNIVERSITY OF PITTSBURGH MEDICAL CENTER** 200 Lothrop Street, Suite C-800 Pittsburgh, PA 15213 **and** **UNIVERSITY OF PITTSBURGH PHYSICIANS** 200 Lothrop Street Pittsburgh, PA 15213 **and** **UNIVERSITY OF PITTSBURGH OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION D/B/A UNIVERSITY OF PITTSBURGH,** 4200 Fifth Avenue Pittsburgh, PA 15260 **Defendants.**	Civil Action No._____ **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** **JURY TRIAL DEMANDED**

COMPLAINT

(False Claims Act, 31 U.S.C. § 3729, *et seq.*; Wrongful Termination)

1. Diana Zaldonis, as Relator, brings this action on behalf of the United States of America under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, against Defendants University of

Pittsburgh Medical Center ("UPMC") and University of Pittsburgh Physicians ("UPP") to recover millions of dollars in false claims to Medicare, Medicaid, TRICARE, and CHAMPVA for surgeries performed by Dr. James Luketich, Dr. Pablo Sanchez, and other surgeons in the Department of Cardiothoracic Surgery as well as for costs associated with clinical trials for medical devices used during lung transplants performed by Dr. Sanchez. These claims were false because they materially omitted the attending physicians' failure to obtain properly the patients' informed consent to surgery and/or participation in clinical trials. Instead, UPMC and UPP falsely certified that the claims complied with Medicare regulations.

2. Diana Zaldonis, individually as plaintiff, also brings this action under 31 U.S.C. § 3730(h) and Pennsylvania's common law cause of action for wrongful termination in violation of public policy against Defendant University of Pittsburgh of The Commonwealth System of Higher Education D/B/A University of Pittsburgh for terminating her employment in retaliation for her reporting to an Institutional Review Board (an independent body responsible for monitoring clinical trials for compliance with rules and standards) Dr. Sanchez's failure to obtain informed consent from a patient for participation in a clinical trial.

I. INTRODUCTION

3. Patients have a right to make informed decisions about their care, in general, and about surgery or participation in clinical trials, in particular. A qualified provider must explain the risks and benefits of surgery and/or participation in a clinical trial and answer any questions the patient might have before obtaining the patient's written consent (collectively hereinafter, "the informed consent process").

4. Medicare's "Condition of participation: Patients rights" generally guarantees a patient's right to informed consent:

> The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment.

42 C.F.R. § 482.13 (2012).

5. According to the U.S. Centers for Medicare & Medicaid Services ("CMS"), "[t]he primary purpose of the informed consent process for surgical services is to ensure that the patient . . . is provided information necessary to enable him/her to evaluate a proposed surgery before agreeing to the surgery." CMS, Revisions to the Hospital Interpretive Guidelines for Informed Consent, 5 (2007).

6. Defendant UPMC promotes the importance of informed consent through the Patient Bill of Rights it publishes on its website in order "to protect the interests and promote the well-being of [its] patients." According to the Bill of Rights, "[e]xcept for emergencies, a patient's physician must obtain the necessary informed consent prior to the start of any procedure or treatment." UPMC, Patient Rights & Responsibilities at UPMC Hospitals (2019) https://www.upmc.com/patients-visitors/patient-info/rights-and-responsibilities.

7. Yet, between at least 2013 and the present, attending surgeons in the UPMC Department of Cardiothoracic Surgery, including but not limited to doctors James Luketich and Pablo Sanchez, improperly delegated the responsibility to obtain patients' consent for surgical procedures to residents, fellows, nurse practitioners, and physician assistants, in violation of federal and state law as well as UPMC policy. These cardiothoracic surgeons often signed a consent form falsely certifying that they had explained to the patient all the information in the consent form, when, in fact, they had not.

8. As a result, surgeons performed complex procedures, including but not limited to lung transplants, esophagectomies, tracheostomies, surgeries for hiatal hernias (such as Nissen and

endoluminal fundoplications), thoracotomies, and removal of pulmonary nodules, that carried risks of serious complications, including death, without properly obtaining the patients' informed consent. Some of these patients, in fact, experienced serious complications, including death.

9. In addition, Dr. Sanchez failed to obtain informed consent properly from lung transplant recipients to participate in certain clinical trials for medical devices used during lung transplants.

10. UPMC falsely billed CMS, the Defense Health Agency (administer of TRICARE), and the Veterans Health Administration Office of Community Care (administer of CHAMPVA) for hospital costs associated with cardiothoracic surgeries performed without proper informed consent as well as for certain costs associated with the clinical trials for medical devices used during transplants without proper patient consent.

11. UPP falsely billed CMS, the Defense Health Agency, and the Veterans Health Administration Office of Community Care for cardiothoracic surgeries performed without proper informed consent.

12. When Plaintiff/Relator Diana Zaldonis alerted an independent body to Dr. Sanchez's failure to obtain informed consent properly from a lung transplant recipient who had participated in a clinical trial for a medical device and had subsequently sued Dr. Luketich, Dr. Sanchez, and UPMC for malpractice, Defendant University of Pittsburgh terminated her employment in retaliation.

II. JURISDICTION AND VENUE

13. This Court has jurisdiction over Counts I through III for violations of the federal False Claims Act under 31 U.S.C. § 3730 and 28 U.S.C. § 1331.

14. This Court also has supplemental jurisdiction over Count IV under 28 U.S.C. § 1367, because Count IV forms part of the same case or controversy as Counts I through III.

15. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) as a place where the Defendants can be found and transact business.

16. The allegations and transactions set forth in this Complaint have not been publicly disclosed through any of the means enumerated in 31 U.S.C. § 3730(e)(4)(A).

17. Prior to filing this Complaint, Plaintiff/Relator voluntarily provided the information set forth herein to the Government.

III. PARTIES

18. Plaintiff the United States of America is acting on behalf of (a) the U.S. Department of Health and Human Services ("HHS") and CMS, which administers the Medicare and Medicaid program, (b) the Department of Defense, including its component, the Defense Health Agency, which administers the TRICARE program, and (c) the Department of Veterans Affairs, including the Veterans Health Administration Office of Community Care, which administers the CHAMPVA program.

19. Plaintiff/Relator Diana Zaldonis was Lead Research Coordinator in UPMC's Cardiothoracic Transplantation division between 2006 and January 2019. During that time, the University of Pittsburgh was her employer. She is currently employed by UPMC as a Clinical Research Coordinator in the UPMC Department of Pulmonary Medicine.

20. Defendant University of Pittsburgh Medical Center maintains a place of business at 200 Lothrop Street, Suite C-00, Pittsburgh, PA 15213, operates under the laws of Pennsylvania, and employs health care professionals, including UPMC employees Pablo Sanchez, M.D., Ph.D.,

FACS, and James D. Luketich, M.D., as well as other physicians, physician assistants, residents, fellows, nurses, technicians, and other agents, staff, and employees.

21. Defendant University of Pittsburgh Physicians maintains a place of business at 200 Lothrop Street Pittsburgh, PA 15213, and is a legal entity operating under the laws of Pennsylvania. UPP is the faculty practice plan (employer entity) through which the University of Pittsburgh School of Medicine faculty provide treatment and care to patients at UPMC.

22. Defendant University of Pittsburgh is a non-profit corporation with its principal place of business at 4200 Fifth Ave, Pittsburgh, PA 15260.

IV. MEDICARE, MEDICAID, TRICARE, AND CHAMPVA REIMBURSEMENT FOR SURGERY AND CLINICAL TRIALS

A. Medicare Reimbursement for Surgery

23. Congress established the Medicare Program in 1965 to provide health insurance coverage for people age 65 or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 426, 426A.

24. The Medicare program comprises four "parts" that cover different services, two of which, Part A and Part B, are relevant here. Medicare Part A generally covers the cost of reasonable and necessary inpatient hospital services, including surgery. Medicare Part B covers the cost of the physician's services such as services to patients who are hospitalized, if the services are medically necessary and personally provided by the physician or, in the case of teaching hospitals, supervised by a physician where strict requirements are satisfied.

25. "Medicare is generally required . . . (for services covered under Part A . . . [and] for services covered under Part B) to pay for services furnished by providers on the basis of reasonable costs . . . " 42 C.F.R. § 413.1 (2014) "The law allows for flexibility in the determination of

reasonable charges to accommodate reimbursement to the various ways in which health services are furnished and charged for." 42 C.F.R. § 405.502 (2006).

26. In order to determine the amount of reimbursement for a surgical procedure, including cardiothoracic surgeries, CMS uses a single predetermined amount and adjusts it, taking into account the location of the provider and the significance of the procedure relative to all other procedures covered by the program. *Id.* CMS will then subtract from that total any amount covered by any other insurance the beneficiary owns, as well as any deductible or copay associated with that other insurance. 42 U.S.C.A. § 1395e.

B. Medicare Reimbursement for Organ Transplantation

27. With respect to organ transplants, Medicare reimburses certified transplant centers ("CTCs") like UPMC[1] for organ transplants by considering two cost components: (1) a specific rate reflecting the typical cost of treating a patient, as determined by a Diagnostic Related Group ("DRG") for the actual organ transplant; and (2) reasonable and necessary costs associated with actually acquiring the organ for transplant, otherwise known as the organ acquisition costs. CMS, Provider Reimbursement Manual, Part 1 – Chapter 31, Organ Acquisition Payment Policy, 31-3 (2016).

28. The DRG is a fixed amount "intended to cover the cost of treating a typical patient" discharged in a particular inpatient treatment category. CMS calculates these rates periodically and releases software to help those requesting reimbursement calculate this component of their prospective reimbursement. CMS, Inpatient PPS PC Pricer, (2019).

29. To determine the organ acquisition costs, each CTC is required to develop standard acquisition charges ("SAC") "which reflect[ ] an average of the total actual costs associated with

[1] UPMC is a transplant center. See Organ Procurement and Transplantation Network, Member Directory for Transplant Centers in Pennsylvania, https://optn.transplant.hrsa.gov/members/member-directory/.

procuring" the required organ from (1) a living donor, and (2) a deceased donor. CMS, Provider Reimbursement Manual, Part 1 – Chapter 31, Organ Acquisition Payment Policy, 31-3 (2016). The SACs (for living and deceased donors) should take into account expenses such as the costs of tissue typing services, costs of physician pre-admission transplant evaluation services, organ recipient registration fees, costs associated with procurement, costs of operating rooms and other ancillary services. *Id.* at 31-4 – 31-5. "Organ acquisition costs incurred by the [CTC] are included on the appropriate organ acquisition cost center on its Medicare cost report (MCR), Form CMS-2552." *Id.* at 31-1.

C. Medicare Reimbursement for Costs Associated with Clinical Device Trials

30. Medicare Part A covers routine costs, as well as reasonable and necessary items and services used to diagnose and treat complications, from participation in qualifying clinical trials for medical devices, including medical devices used during clinical trials for lung transplants. 42 U.S.C. § 1395y(m)(1) (2018); 42 C.F.R. § 405.211 (2015).

31. According to CMS, Medical Coverage – Clinical Trials, Final National Coverage Decision:

> Routine costs in clinical trials include:
>
> - Items or services that are typically provided absent a clinical trial (e.g., conventional care);
> - Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
> - Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service--in particular, for the diagnosis or treatment of complications.

32. Routine costs include, for example, "physician fee schedule, lab fee schedule, durable medical equipment fee schedule, reasonable charge, etc." CMS, Medicare Claims Processing Manual, Ch. 32, § 69.2, p. 81 (2019).

D. Medicaid Reimbursement for Surgery

33. Congress created Medicaid at the same time it created Medicare in 1965 by adding Title XIX to the Social Security Act. Medicaid is a public assistance program that provides payment of medical expenses primarily for low-income patients. Funding for Medicaid is shared between the federal and state governments. The federal government also separately matches certain state expenses incurred in administering the Medicaid program. While specific Medicaid coverage guidelines vary from state to state, Medicaid's coverage is generally modeled after Medicare's coverage. According to CMS, "[w]hen services are furnished through institutions that must be certified for Medicare, the institutional standards must be met for Medicaid as well." CMS, Quality, Safety & Oversight – Certification & Compliance, *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Certificationand Complianc/index.html?redirect=/certificationandcomplianc/02_ascs.asp.

E. TRICARE and CHAMPVA Reimbursement for Surgery

34. TRICARE "combines the resources of military hospitals and clinics with civilian health care networks" to provide healthcare for (1) uniformed service members and their families; (2) National Guard or Reserve members and their families; (3) certain former spouses; (4) medal of honor recipients and their families; (5) survivors; (6) certain other individuals eligible under the Defense Enrollment Eligibility Reporting System. Health.mil, *TRICARE Health Program*, (2019) https://health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Access-to-Healthcare/TRICARE-Health-Plan; TRICARE, Eligibility, (2019), available

at https://tricare.mil/Plans/Eligibility. As of January 1, 2018, TRICARE administration is managed at a regional level, each region having its own managed care support contractor ("MCSC"). The MCSC for the east region, which includes Pennsylvania, is Humana Military. Health.mil, *Information for TRICARE Providers*, (2019), https://health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Access-to-Healthcare/Information-for-TRICARE-Providers.

35. The Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA") is a comprehensive health care program for retired members of the uniformed services. U.S. Department of Veteran Affairs, *Community Care*, (2019) https://www.va.gov/COMMUNITYCARE/programs/dependents/champva/index.asp. The Veterans Health Administration Office of Community Care administers the program, which covers "most health care services and supplies that are medically and psychologically necessary." *Id.*

36. TRICARE and CHAMPVA regulations relating to coverage of claims by providers and physicians are substantially similar to the Medicare provisions applicable to this disclosure. For example, under the CHAMPVA regulations, "all patient care furnished under title 38 U.S.C. shall be carried out only with the full and informed consent of the patient or, in appropriate cases, a representative thereof." 38 C.F.R. § 17.32(b) (2009). Informed consent must be obtained and appropriately documented "for all diagnostic and therapeutic treatments or procedures that: (i) Require the use of sedation; (ii) Require anesthesia or narcotic analgesia; (iii) Are considered to produce significant discomfort to the patient; (iv) Have a significant risk of complication or morbidity; or (v) Require injections of any substance into a joint space or body cavity." 38 C.F.R. § 17.32(d) (2009). "Informed consent" is defined as "the freely given consent that follows a careful explanation by the practitioner to the patient or the patient's surrogate of the proposed

diagnostic or therapeutic procedure or course of treatment." 38 C.F.R. § 17.32(c) (2009). Importantly, the regulation requires that:

> The practitioner, who has primary responsibility for the patient or who will perform the particular procedure or provide the treatment, must explain in language understandable to the patient or surrogate the nature of a proposed procedure or treatment; the expected benefits; reasonably foreseeable associated risks, complications or side effects; reasonable and available alternatives; and anticipated results if nothing is done. The patient or surrogate must be given the opportunity to ask questions, to indicate comprehension of the information provided, and to grant permission freely without coercion.

Id.

V. PROPER INFORMED CONSENT IS A MEDICARE CONDITION OF PARTICIPATION AND PAYMENT FOR COVERED SURGERIES.

37. "Hospitals are required to be in compliance with the Federal requirements set forth in the Medicare Conditions of Participation (CoP) in order to receive Medicare/Medicaid Payment." CMS, State Operations Manual: Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, Introduction, p. 3 (2018) (Rev. 37, effective Oct. 17, 2008).

38. Medicare's "Condition of participation: Surgical services" states, "A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies." 42 C.F.R. § 482.51(b)(2) (2008). CMS' interpretation of this regulation states, "Hospitals must assure that the practitioner(s) responsible for the surgery obtain informed consent from patients in a manner consistent with the hospital's policies governing the informed consent process. . . . If there are additional requirements under State law for informed consent, the hospital must comply with those requirements." CMS, *State Operations Manual, App'x A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, A-0955*, Interpretive Guidelines §482.51(b)(2), p. 466-67 (2018) (Rev. 37, effective Oct. 17, 2008).

39. Further, CMS' "Condition of participation: Medical record services" requires a hospital's medical record to include "[p]roperly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent." 42 C.F.R. § 482.24(c)(4)(v) (2012). CMS has interpreted this regulation to mean that "[a]n informed consent form, in order to be properly executed, **must be consistent with hospital policies as well as applicable State and Federal law or regulation**." CMS, *State Operations Manual, App'x A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals*, A-0466, Interpretive Guidelines §482.24(c)(4)(v), p. 289 (2018) (Rev. 95, effective Jun. 7, 2013) (emphasis added).

40. CMS, through Medicare contractors (carriers, fiscal intermediaries, or Medicare Administrative Contractors) has consistently denied claims, and HHS has excluded providers from participating in Medicare, for failure to obtain informed consent properly from patients. *See, e.g.*, *In the Cases of: Nazareno Med. Hospice Fajardo, Caguas, Cayeys*, DAB CR386, 1995 WL 543450 (1995) (H.H.S. Aug. 18, 1995) (where "Health Care Financing Administration (HCFA) terminated the petitioner's participation in Medicare, based on its determination that the Petitioner failed to comply with conditions of participation in the Medicare program," including informed consent); *Bernard J. Burke, M.D.*, DAB 1576, 1996 WL 329301 (1996) (H.H.S. May 17, 1996) (H.H.S. Departmental Appeals Board upheld ALJ's five-year exclusion from participation in Medicare because petitioner, among other things, "failed to meet the professionally recognized standard of care by not getting informed consent to perform a procedure on the patient"); *W. Care Mgmt. Corp., d/b/a Rehab Specialties Inn*, DAB 1921, 2004 WL 1235824 (2004) (H.H.S. May 10, 2004) (H.H.S. Departmental Appeals Board upheld two civil money penalties imposed by CMS for alleged deficiencies, including failure to obtain timely informed consent to the administration

of certain drugs); *Guaynabo Hospice Care*, Inc., DAB CR374, 1995 WL 317324 (1995) (H.H.S. May 8, 1995) (petitioner's appeal of HCFA termination of Petitioner's Medicare contract for failure to comply with four conditions of participation, one of which was informed content; appeal was moot); *In the Case of Caris Mpi, Inc. (Appellant) (Beneficiary) Noridian Admin. Servs., LLC (Contractor) Claim for Supplementary Med. Ins. Benefits (Part B)*, No. Docket Number: M-12-648, 2012 WL 2119165, at *8 (H.H.S. Apr. 24, 2012) (Remanding to ALJ for further consideration where ALJ found that the provider was entitled to payment for molecular diagnostic laboratory testing services provided to the beneficiaries. Remanded because ALJ had not sufficiently considered, among other things, whether billing provider submitted sufficient supporting documentation, which included "a signed informed consent indicating that the patient was informed of "issues and information associated with genetic testing." (emphasis in original)).

VI. PROPER INFORMED CONSENT IS A MEDICARE CONDITION OF PAYMENT FOR REIMBURSABLE COSTS ASSOCIATED WITH CLINICAL DEVICE TRIALS.

41. The Medicare requirements for informed consent by a patient who agrees to participate in a clinical trial for a medical device are substantially the same as those for informed consent for surgery. Medicare regulations require the informed consent procedure for participation in a clinical trial for a medical device to be consistent with federal and state law as well as hospital policy. 42 C.F.R. § 482.24(c)(4)(v) (2012); CMS, State Operations Manual: Appendix A, at A-0465, Interpretive Guidelines §482.24(c)(4)(v), p. 289.

42. In addition, FDA regulations – incorporated as a condition of payment through CMS' requirement that informed consent be conducted in a manner consistent with federal regulations – state that "no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of

the subject or the subject's legally authorized representative." 21 CFR Part 50.20 (1999). An "investigator" under 21 CFR Part 50 is the "individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered . . . or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team." 21 C.F.R. § 50.3 (2013) (includes "medical device for human use" as an example of "test article").

43. Thus, informed consent for participation in a clinical trial for a medical device must be obtained either by the person in charge of the study (i.e., the principal investigator of a device trial) or by an investigator "under whose immediate direction the test article is administered" (i.e., the attending physician).

VII. FEDERAL LAW AND PENNSYLVANIA LAW REQUIRE MEDICAL RECORDS TO BE ACCURATE.

44. Medicare regulations require medical records to be "accurately written, promptly completed, properly filed and retained, and accessible." 42 C.F.R. § 482.24 (2012).

45. Similarly, Pennsylvania law requires a physician to "maintain medical records for patients which accurately, legibly and completely reflect the evaluation and treatment of the patient." 49 Pa. Code § 16.95(a).

46. Thus, a doctor may not sign an informed consent form falsely certifying that he has explained to the patient all of the information contained in the form when, in fact, he has not.

VIII. PENNSYLVANIA LAW AND UPMC POLICY REQUIRE AN ATTENDING PHYSICIAN TO OBTAIN INFORMED CONSENT PRIOR TO SURGERY AND PRIOR TO PARTICIPATION IN A CLINICAL DEVICE TRIAL.

47. On June 20, 2017, the Supreme Court of Pennsylvania held that "[T]he duty to obtain a patient's informed consent is a non-delegable duty owed by the physician conducting the surgery or treatment." *Shinal v. Toms*, 162 A.3d 429, 453 (Pa. 2017).

48. UPMC advised its providers of the decision in *Shinal* and provided guidance on compliance with the decision.

49. UPMC's policy on informed consent, in accord with *Shinal*, states:

> 1. Except as noted below, **Attending Physicians Are Responsible For Obtaining Informed Consent.** The attending physician overseeing the patient's care is responsible for and must obtain informed consent for all procedures that require informed consent. The attending shall sign the consent form after the consent discussion occurs. Residents or Fellows may only obtain informed consent for blood or blood products or for procedures their departments have deemed them qualified to perform.
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> 2. **Advanced Practice Providers or Medical Students May Not Obtain Informed Consent** for the enumerated items in IIA [including "[p]erforming surgery" and "[u]sing an experimental device"]. Advanced Practice Providers may obtain consent for and perform procedures for which they are credentialed to do.
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> 3. **Nurses May Not Obtain Informed Consent.**

UPMC Policy and Procedure Manual, HS-RI1302, *Patient Informed Consent*, III (bold in original).

50. Both *Shinal* and UPMC policy on informed consent apply to both surgery and participation in clinical trials for medical devices. *See Shinal v. Toms*, 162 A.3d 429, 457 n.1 (Pa. 2017); UPMC Policy and Procedure Manual, HS-RI1302, *Patient Informed Consent*, II(A).

IX. DR. JAMES LUKETICH AND DR. PEDRO SANCHEZ

A. Dr. James Luketich

51. Dr. Luketich is the Chairman of UPMC's Department of Cardiothoracic Surgery. As Chairman, he oversees 23 specialty surgeons in four divisions: (1) Cardiac Surgery and Heart Transplant, (2) Pediatric Cardiac Surgery, (3) Thoracic and Foregut Surgery, and (4) Lung Transplant and Lung Failure.

52. Dr. Luketich, who also holds an appointment as Henry T. Bahnson Professor of Cardiothoracic Surgery at the University of Pittsburgh and serves as Chairman of the Division of Thoracic and Foregut Surgery, maintains total control of the Department of Cardiothoracic

Surgery. He decides who is hired, who is fired, how to allocate funding, and how to staff the department. He also determines call and rotation schedules, selects and oversees residents and fellows, and sets the supervisory reporting structure.

53. Dr. Luketich reports directly to UPMC CEO Jeffrey Romoff.

54. In 2018, Dr. Luketich was the fifth highest paid employee of UPMC's 87,000 employees, earning $2.5 million, behind only the CEO, the president of the UPMC Health Plan, the chief of staff, and the chief medical/chief science officer.

B. Dr. Pablo Sanchez

55. Dr. Sanchez is the current Surgical Director of UPMC's Division of Lung Transplant and Lung Failure within the Department of Cardiothoracic Surgery.

56. Dr. Sanchez signed his contract to begin at UPMC in July 2017, arrived at UPMC in or about September 2017, and received permission to perform lung transplants in or around October 2017.

57. When he arrived at UPMC, Dr. Sanchez had little direct experience performing lung transplants. On information and belief, Dr. Sanchez had only performed three lung transplants as a primary surgeon prior to joining UPMC.

58. Dr. Luketich elevated Dr. Sanchez into his current position in April 2018, placing him over the more experienced prior Surgical Director.

X. DOCTORS IN UPMC'S DEPARTMENT OF CARDIOTHORACIC SURGERY DID NOT COMPLY WITH FEDERAL LAW, STATE LAW, AND UPMC POLICY WHEN OBTAINING PATIENTS' CONSENT TO SURGERY AND PARTICIPATION IN CLINICAL TRIALS FOR MEDICAL DEVICES.

59. Between September 2013 and the present, doctors in UPMC's Department of Cardiothoracic Surgery, including but not limited to doctors Luketich and Sanchez, falsely and fraudulently signed UPMC consent forms certifying that they had "explained to the patient . . . all

of the information contained in this consent form" when, in fact, they had not, in violation of federal and state law.

60. In addition, from June 20, 2017 to the present, doctors in UPMC's Department of Cardiothoracic Surgery, including but not limited to doctors Luketich and Sanchez, improperly delegated responsibility for the informed consent process to fellows, residents, nurses, and physician assistants, all of whom were unqualified to lead the informed consent process according to law and UPMC policy.

A. Dr. Luketich Failed to Obtain Informed Consent Properly for Many of His Surgeries.

61. Between June 20, 2017 and the present, Dr. Luketich improperly delegated responsibility to obtain informed consent from his patients for a wide range of cardiothoracic surgeries, including but not limited to esophagectomies, tracheostomies, surgeries for hiatal hernias (such as Nissen and endoluminal fundoplications), thoracotomies, and removal of pulmonary nodules.

62. He has done this in, at least, two ways: (1) instructing residents and other subordinates to obtain consent from inpatients; and (2) instructing "superfellows" to obtain informed consent from clinic patients.

63. As Chairman of the Department of Cardiothoracic Surgery, Dr. Luketich had, and continues to have, the power to order others to do the tasks he considers beneath him, including participating in clinic, rounding, and obtaining informed consent. Dr. Luketich makes little effort to personally engage with patients prior to surgery. At times, a patient will encounter Dr. Luketich for the first time while under anesthesia in the operating room having never had the opportunity to ask him about the life-changing surgery he is about to perform.

1. Dr. Luketich instructed residents and other subordinates to obtain consent from inpatients.

64. At times, UPMC admits patients to the hospital prior to cardiothoracic surgery. These inpatients will wait in a hospital bed prior to surgery. (Other times, patients arrive for surgery from home.)

65. UPMC admits patients who need cardiothoracic surgery through a number of channels: a patient might be transferred from another hospital for the purpose of receiving surgery at UPMC; a patient admitted to UPMC for reasons other than surgery might require cardiothoracic surgery during the course of their inpatient stay; or, UPMC might admit a patient after postponing/rescheduling cardiothoracic surgery for a patient who has already arrived in the hospital from home.

66. Inpatients typically see their doctors during "rounds" prior to surgery. Rounding involves teams of providers who visit patients, one after the other, to check on their wellbeing, to make sure they are prepared for surgery, and to adjust their medications, amongst other tasks. Typically, providers answer inpatient questions about surgery and obtain inpatient consent to surgery during rounds.

67. Since it is not Dr. Luketich's practice to round, typically he will not see inpatients during their inpatient stays prior to surgeries that he performs. Instead, at Dr. Luketich's direction, residents – either general surgery residents or cardiothoracic surgery residents – will meet with the patients during their inpatient stays and obtain their consent to surgery. Thus, residents, some of whom are not even training in cardiothoracic surgery, will explain the risks and benefits of cardiothoracic surgery to Dr. Luketich's patients and then sign the consent forms alongside the patients' signatures.

68. On information and belief, when a resident does not obtain consent from an inpatient awaiting surgery by Dr. Luketich, superfellows (see discussion of superfellows below), fellows, nurse practitioners, and physician assistants conduct the informed consent process, in violation of federal and state law and UPMC policy. While superfellows, fellows, and residents may sign the consent form, nurse practitioners and physician assistants typically do not, leaving the signature to a physician, who will sign the form whether or not the physician has participated in the consent process.

69. At times, Dr. Luketich signed the consent to surgery form next to the name of the fellow, superfellow, resident, nurse practitioner, or physician assistant who initially signed the consent form. Each time, he placed his signature under a statement that read, "I have explained to the patient signing above all of the information contained in this consent form." In fact, Dr. Luketich had not met with many of these patients at all and had not explained any of the information contained in the consent form, in violation of federal and state law.

2. Dr. Luketich instructed "superfellows" and other subordinates to obtain consent from patients during clinic hours.

70. During clinic hours, providers encounter outpatients, typically by appointment, for a variety of conditions, often developing a plan of treatment that may include surgery.

71. Dr. Luketich is expected to attend the Digestive Disorder Clinic on Tuesdays on the third floor of UPMC Presbyterian and also clinic at the UPMC Hillman Cancer Center on Thursdays. However, he rarely does.

72. During clinic hours, Dr. Luketich is typically in surgery and sends "superfellows" in his absence.

73. Doctors who have just completed ACGME[2] fellowships in cardiothoracic surgery participate in an additional one-year fellowship in minimally invasive cardiothoracic surgical techniques at Dr. Luketich's insistence. During this additional fellowship year, these doctors are commonly referred to as "superfellows." Dr. Luketich conditions completion of the ACGME fellowship upon a commitment to participate in the superfellows program, during which the superfellows are paid less than what they would earn on the open market and Dr. Luketich makes them perform the work that he does not want to do himself. The graduating fellows agree to this arrangement to ensure completion of their program and because they dare not say, "no," to Dr. Luketich, who could refuse to offer them a positive recommendation or otherwise create impediments to their nascent careers.

74. Superfellows remain in an educational program, and UPMC does not permit them to lead cardiothoracic surgeries without supervision by an attending.

75. The superfellows see patients in clinic and at that time obtain their consent to surgery to be performed by Dr. Luketich. The superfellows sign the consent forms themselves, in violation of federal and state law as well as UPMC policy.

76. On information and belief, when superfellows are not available to conduct the informed consent process with Dr. Luketich's patients, fellows, residents, nurse practitioners, and physician assistants conduct the process, in violation of federal and state law and UPMC policy. While superfellows, fellows, or residents may sign the consent form, nurse practitioners and physician assistants typically do not, leaving the signature to a physician, who will sign the form whether or not the physician has participated in the consent process.

[2] ACGME stands for Accreditation Council for Graduate Medical Education, which accredits residency and fellowship programs at medical schools.

77. As with inpatients, at times, Dr. Luketich has signed the consent to surgery form next to the name of the superfellow, fellow, resident, nurse practitioner, or physician assistant who initially signed the consent form. Each time, he placed his signature under a statement that read, "I have explained to the patient signing above all of the information contained in this consent form." In fact, Dr. Luketich had not met with many of these patients at all and had not explained any of the information contained in the consent form. Thus, Dr. Luketich made false statements on the forms, in violation of federal and state law.

B. Dr. Sanchez Failed to Obtain Informed Consent Properly for Many of His Lung Transplants and for Participation in Clinical Trials for Medical Devices Used During Lung Transplants.

78. From in or about October 2017, when Dr. Sanchez first began performing lung transplants, to the present, Dr. Sanchez failed to obtain informed consent properly for lung transplants. Dr. Sanchez, like his mentor and benefactor Dr. Luketich, instructed non-authorized staff, including residents, fellows, nurse practitioners, and physician assistants, to obtain transplant patients' consent on his behalf and in his absence.

79. From in or about October 2017 to the present, Dr. Sanchez also failed to obtain informed consent properly from patients for participation in clinical trials for medical devices that he used during lung transplants that he performed. Like Dr. Luketich, Dr. Sanchez considered this task to be beneath him, telling Ms. Zaldonis that he didn't "have time" to obtain informed consent from clinical trial patients. He asked Ms. Zaldonis to obtain consent from patients, and she refused, knowing that it was against the law and hospital policy.

1. Dr. Sanchez instructed residents and other subordinates to obtain consent to surgery from lung transplant patients.

80. The lung transplant process is a long one. Patients often wait for months for lungs to become available for transplant. During this time, UPMC makes available educational

presentations about the transplant procedure for patients considering qualifying for the transplant waiting list (These patients may or may not qualify for the list, and, if they qualify, they may or may not receive a donor lung for months or years.).

81. For these presentations, a resident, fellow, or, occasionally, an attending physician will walk through a PowerPoint slide show for a class of potential lung recipients. After the presentation, a pre-lung transplant coordinator will hand out informed consent forms titled "Lung Transplant Adult Consent Form." The patients sign the forms, and an attending countersigns sometime after the presentation. Thus, the attending typically does not make the presentation and does not sit down with the individual patient to go over the potential procedure one-on-one answering questions. This process, which takes place months or years before surgery, does not comply with state law, UPMC policy, or Medicare regulations for proper informed consent procedure.

82. However, there is a second consent form, different from the first form, that is signed by lung transplant patients on or shortly before the day of surgery. A second form is necessary both to make sure that the patient has not changed his/her mind and also to specify the exact surgery to be performed (for example, whether the patient receives one lung or two), which cannot be fully predicted until the lungs become available. The surgery must be described in detail in the informed consent form, because the patient must be informed before consenting and also because the form is used during the surgical "time out" right before surgery. That is, the form is read during the "time out" so that all of the providers agree that they are about to perform the correct surgery and there are no mistakes about, for example, whether to replace the right or left lung.

83. There are two versions of the second form. One is called "Organ Transplant Surgery Consent Form" and the other is called "Consent to Surgery or Special Procedure."

84. Dr. Sanchez does not review the second form (either version) with the patient or sign it in the patient's presence. Instead, he improperly delegates the task.

85. Once lungs become available, the outpatient pre-transplant coordinator (a registered nurse) calls the patient and instructs him/her to come to the hospital. The transplant coordinator then emails the lung transplant listserve (which includes lung transplant surgeons, lung transplant pulmonologists, infectious disease physicians, clinical researchers, post-lung transplant coordinators/nurses, and others) to ask who will be obtaining the patient's consent, history and physical, and orders (such as medications). Residents, and occasionally fellows, regularly reply to the listerserve to notify the group that they will obtain consent. Often, Dr. Sanchez sends emails to the listserve pointing out that informed consent is missing or needed, and residents respond to confirm that they will obtain consent.

86. Once admitted to UPMC Presbyterian hospital, the patient meets with a resident, fellow, nurse practitioner, or physician assistant for a history and physical ("H&P"), who at that time conducts the consent process with the patient, in violation of law and UPMC policy. The patient signs the second consent form. The resident or fellow might sign as well, or otherwise leave the signature line blank for Dr. Sanchez to sign later (typically, a physician assistant will not sign and will leave the signature line for the physician blank). At times, both Dr. Sanchez and the subordinate will sign the informed consent form.

87. Dr. Sanchez has falsely signed these consent forms under the statement "I have explained to the patient signing above all of the information referred to in this consent form," in violation of federal and state law.

88. At times, Dr. Sanchez has pre-signed informed consent forms to be used by his residents, fellows, and/or physician assistants. On more than one occasion, the Director of

Transplant Services, who oversaw the pre- and post-heart and lung transplant coordinators, found informed consent forms pre-signed by Dr. Sanchez left in a stack at a station on floor 9D. That is the area with beds for lung transplant patients both pre- and post-transplant. Along the hallway is a station (an L-shaped counter with chairs and computers) used by residents, social workers, and staff nurses. The stack of pre-signed forms was left for residents, fellows, and/or physician assistants to pick up, and take with them when meeting with lung transplant patients just prior to operation. The residents/fellows/physician assistants asked the patients to countersign the forms pre-signed by Dr. Sanchez. The Director of Transplant Services was so angry about this practice that on more than one occasion she shredded the pre-signed forms.

2. Dr. Sanchez instructed residents and other subordinates to obtain consent to participate in clinical trials for medical devices used during lung transplants.

89. Between October 2017 and the present, Dr. Sanchez worked on at least two studies as the designated co-investigator: (1) the Novel Lung Trial: Normothermic Ex Vivo Lung Perfusion (Evlp) As An Assessment Of Extended/Marginal Donor Lungs, and Extending Preservation, and (2) Assessment Time of Donor Lungs Using the Toronto EVLP System™ at a Dedicated EVLP Facility. Ms. Zaldonis was the coordinator for these studies, and Dr. Jonathan D'Cunha served as the Principal Investigator.

90. Under Medicare regulations, state law, and hospital policy, the principal investigator (Dr. D'Cunha, on the two studies named above) or the physician performing the lung transplant with the assistance of the investigational device (Dr. D'Cunha or Dr. Sanchez) had to obtain the patient's informed consent to participate in the device trial. As a matter of UPMC practice, the surgeon performing the lung transplant was responsible for obtaining informed

consent, including signing the Informed Consent and HIPAA Authorization Form for Subject Participation in a Research Study.

91. Dr. Sanchez did not properly exercise his authority to obtain informed consent from his patients for participation in the clinical studies, which is to say he improperly delegated the task to subordinates. His residents, fellows, nurse practitioners, and physician assistants typically obtained consent from patients during the H&P, at the same time they obtained consent to surgery, in violation of law and UPMC policy.

92. Dr. Sanchez falsely signed the clinical study consent forms himself under the statement "I, the undersigned, certify that I have fully explained all available information for this research study to the patient named above, have answered their questions, and will provide the patient with a copy of this signed and dated informed consent form." In fact, he had not explained all available information for the research studies to his patients. Dr. Sanchez made these false certifications in violation of federal and state law.

C. Additional Surgeons in UPMC's Department of Cardiothoracic Surgery Failed to Obtain Informed Consent Properly for Surgeries They Performed.

93. As Chairman of the Department of Cardiothoracic Surgery, Dr. Luketich set an example for others in the department and set the tone and culture for the department. As a result, in addition to Dr. Sanchez, some of the other surgeons in the department followed Dr. Luketich's example and delegated responsibility for the informed consent process to subordinates, in violation of law and UPMC policy.

94. For example, Dr. Inderpal Sarkaria, Director of Thoracic Robotic Surgery, like Dr. Luketich, did not typically round and delegated responsibility for the informed consent process to subordinates who are not permitted by law or UPMC policy to obtain informed consent from

patients. On information and belief, patients have complained about him failing to properly provide them with relevant information about their surgeries prior to surgery.

95. In addition, in 2017 or 2018, Dr. Thomas Gleason, currently Chief of the Division of Cardiac Surgery within the Department of Cardiothoracic Surgery, failed to obtain informed consent from a patient during a procedure at UPMC Shadyside to insert a dialysis catheter in a patient's neck. After the patient died during surgery, Dr. Gleason instructed a resident to enter a note into the medical record stating that Dr. Gleason had explained the procedure to the patient and obtained consent when, in fact, he had not. The resident reported the incident through the risk master software (the computer system used to report deviations from protocol at UPMC) and told Dr. Luketich that she had done so. Dr. Luketich told the resident that he would "look into it." That was the last the resident heard of the matter.

XI. UPMC AND UPP FILED FALSE CLAIMS FOR REIMBURSEMENT UNDER THE MEDICARE, MEDICAID, TRICARE, AND CHAMPVA PROGRAMS.

96. According to UPMC's Internal Revenue Form 990, Return of Organization Exempt From Income Tax, UPMC received $2,049,406,778 in revenue from Medicare for the fiscal year ending June 30, 2017.

97. According to Medicare Provider Utilization and Payment Data, Medicare made payments to UPMC for surgeries performed in UPMC's Department of Cardiothoracic Surgery totaling as follows: $23,651,077.94 in 2014, $26,190,576.95 in 2015, $21,916,403.93 in 2016, and $21,768,559.13 in 2017.[3] (Medicare has not made data public for 2013, 2018, or 2019 (to date).)

[3] In reality, the total Medicare reimbursements summarized here are artificially low. Medicare groups similar surgeries into "Diagnosis Related Groups" ("DRG"). The reimbursement totals are associated with DRGs that UPMC providers performed in the Department of Cardiothoracic Surgery. Since CMS provides Medicare data only for the 100 most popular DRGs, the total amounts provided likely do not include payments for several surgeries performed in the Department of Cardiothoracic Surgery.

98. Based on the scheme to submit false claims described herein, there is reliable indicia that lead to a strong inference that UPMC and UPP submitted claims to CMS (under both Medicare and Medicaid), the Defense Health Agency (under TRICARE), and the Veterans Health Administration Office of Community Care (under CHAMPVA) between 2013 and the present for surgeries, including but not limited to lung transplants, performed by surgeons in the Department of Cardiothoracic Surgery, including but not limited to doctors Luketich and Sanchez, as well as for routine costs of care associated with clinical trials for medical devices used during lung transplants, where informed consent was not obtained properly from the patient, in violation of federal and state law as well as UPMC policy.

99. UPP also submitted false claims to CMS for physician's services associated with the same surgeries.

100. When submitting false claims to CMS, the Defense Health Agency, and the Veterans Health Administration Office of Community Care, UPMC used CMS Form 1450 or its electronic equivalent, Form 837I, and UPP used CMS Form 1500 or its electronic equivalent, Form 837P. By signing these forms, UPMC and UPP certified that the forms were accurate, complete, and/or in compliance with laws and regulations.

101. The certification that appears on the back of Forms 1450 (and, on information and belief, on Forms 837I) that UPMC submitted read, "Submission of this claim constitutes certification that the billing information as shown on the face hereof is true, accurate and complete. That the submitter did not knowingly or recklessly disregard or misrepresent or conceal material facts." In fact, the billing information on the Forms 1450 related to surgeries relevant here were not true, accurate and complete, because they materially omitted reference to failures to properly obtain informed consent from patients. By filing claims for surgeries where attending surgeons in

the Department of Cardiothoracic Surgery did not obtain informed consent properly, UPMC and UPP rendered false the certifications in the corresponding Forms 1450 and 837I.

102. Similarly, the certification on the back of Forms 1500 (and, on information and belief, on Forms 837P) that UPP submitted read:

> In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law); 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE . . . .

The Form 1500 further warned, "Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties." By filing claims for surgeries where attending surgeons in the Department of Cardiothoracic Surgery did not obtain informed consent properly, UPMC and UPP rendered false the certifications in the corresponding Forms 1500 and 837P.

103. UPMC and UPP also certified compliance with applicable laws and regulations at the time of enrollment in Medicare. Providers are required to complete Form 855A, Medicare's Enrollment Application, which delineates the penalties for submitting false information under several statutes including, the Federal False Claims and the Social Security Acts, among others. Section 15 of Form 855A requires each of the provider's authorized officials to certify, among other things, that s/he: "understand[s] that payment of a claim by Medicare is conditioned

upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare." Each authorized official must further certify that s/he "will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and [ ] will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity." Finally, "By his/her signature(s), an authorized official binds the provider to all of the requirements listed in the Certification Statement and acknowledges that the provider may be denied entry to or revoked from the Medicare program if any requirements are not met." By filing claims for surgeries where attending surgeons in the Department of Cardiothoracic Surgery did not obtain informed consent properly, UPMC and UPP rendered false the certifications in their Forms 855A.

104. In sum, UPMC and UPP submitted claims to CMS and other government payors arising out of surgeries performed by surgeons in the Department of Cardiothoracic Surgery without obtaining informed consent properly. These claims falsely certified compliance with CMS regulations, including those requiring them to obtain their patients' informed consent properly prior to surgery. These false claims caused Medicare and other government payors to remit funds to UPMC and UPP.

XII. UPMC AND UPP ACTED KNOWINGLY.

105. Doctors Luketich and Sanchez, and other surgeons in the Department of Cardiothoracic Surgery, did not hide their unlawful approach to informed consent. They openly instructed their subordinates to obtain informed consent. Nearly everyone in the Department of Cardiothoracic Surgery knew that Dr. Luketich did not attend clinic. Dr. Sanchez directed residents and others to obtain consent through messages sent to a listserve seen by nearly everyone involved

in lung transplants, from nurses to attending physicians. In short, the practice of using subordinates to obtain informed consent was well known throughout the Department.

106. Complaints about the practice, to the extent Ms. Zaldonis is aware of them, were infrequent as few dared question Dr. Luketich or doctors, like Dr. Sanchez, who enjoyed Dr. Luketich's protection. However, as discussed above in paragraph 95 above, in 2017 or 2018, a resident used the risk master software to report Dr. Gleason's failure to obtain informed consent from a patient who died during surgery as well as his subsequent attempt to cover up his failure. The resident also reported the matter directly to Dr. Luketich. The resident is not aware of any steps that Dr. Luketich or anyone else in the Department took to address the matter. The approach to informed consent in the department did not change. That is unsurprising, because the man she complained to, the man at the top, was Dr. Luketich, and he was the primary offender.

107. On several occasions, Dr. Sanchez's improper practices came to the attention of the Clinical Research Associates (CRAs) contracted by the sponsors of the two clinical trials for medical devices used in lung transplants that he co-investigated. The CRAs monitored the trials' compliance with rules and regulations. Lung Bioengineering, sponsor of the Toronto EVLP trial, hired CTI Clinical Trial and Consulting Services to provide CRAs to monitor its trial.

108. During a monitoring visit in 2018, CTI CRA Deborah Gawin uncovered a number of improperly executed informed consent forms. As required by hospital policy, Ms. Zaldonis reported the consent form irregularities (called "protocol deviations") to the Advarra Institutional Review Board. In late August or early September 2018, at the behest of Ms. Gawin, Ms. Zaldonis and Dr. D'Cunha met with Dr. Sanchez to discuss and attempt to remedy Dr. Sanchez's persistent consent protocol deviations. Because Dr. Sanchez had consistently failed to obtain informed consent from his patients himself, the meeting became tense, and at the conclusion of the meeting,

Dr. Sanchez said to Ms. Zaldonis that the whole meeting was "ridiculous." He defended his conduct, saying, "I didn't kill anyone."

109. A few weeks after this meeting, Ms. Zaldonis and Dr. D'Cunha held a conference call with Dr. Jordan Shin, Vice President of Lung Biotechnology (parent company of Lung Bioengineering) to discuss Dr. Sanchez and his issues with informed consent. Dr. Shin suggested that Ms. Zaldonis and Dr. D'Cunha create a corrective action plan for Dr. Sanchez. Ms. Zaldonis does not know whether the corrective action plan was implemented, because she was, shortly thereafter, dismissed from the department. However, a letter from CTI CRA Deborah Gawin dated December 21, 2018, noted the problem with informed consent, designating it a "major protocol deviation" and stating:

- **Action:** This is a major protocol deviation and has been submitted to your IRB.
- Your corrective action plan is primarily focused on the informed consent process and documentation. You have conducted informed consent training with the Co-Investigator, as documented by the Note to File. The importance of prompt reporting of informed consent deviations has been discussed with your site and re-training will be conducted by the Sponsor as part of the current CAPA process.
- Please complete and submit a protocol deviation form to document the deviation and corrective action that has taken place and planned for the future.

110. Further, doctors Luketich and Sanchez were managers and executives within UPMC: Luketich as Chairman of the Department of Cardiothoracic Surgery and Sanchez as Surgical Director of the Division of Lung Transplant and Lung Failure. Accordingly, the knowledge of doctors Luketich and Sanchez is imputed to UPMC.

111. Finally, since doctors Luketich and Sanchez, as well as other surgeons in the Department of Cardiothoracic Surgery, were acting within the scope of their employment when

they operated on patients without obtaining their consent properly, their employers, UPMC and UPP, were vicariously responsible for their actions.

XIII. EXAMPLES OF SURGERIES PERFORMED WITHOUT PROPER INFORMED CONSENT.

Example 1: Patient W.K

112. On September 4, 2018, Dr. Brett F. Duncan, a fellow supervised by Dr. Sanchez, performed a history and physical ("H&P") on a Medicare beneficiary with the initials W.K. prior to a lung transplant performed the same day.

113. Dr. Duncan electronically signed the H&P note on the day of the H&P and wrote "Consent obtained" in the section of the note titled "Assessment and Plan," indicating that he (Dr. Duncan) had obtained consent from the patient. Dr. Sanchez did not electronically sign the note, which means that he did not participate in obtaining consent.

114. Dr. Sanchez, however, signed the informed consent form, falsely certifying that he had "explained to the patient signing above all of the information referred to in this consent form."

Example 2: Patient C.R.

115. Dr. Sanchez's operative report for C.R., a Medicare beneficiary, is dated July 24, 2018 at 7:00pm. However, next to Dr. Sanchez's signature on the informed consent form is a date and time in his handwriting of July 27, 2018 at 10:41pm, three days *after* surgery. By signing the form, Dr. Sanchez falsely certified that he had "explained to the person signing above all of the information contained in this consent form."

Example 3: Patient B.K.

116. On March 5, 2019, Dr. Matthew Pommerening, a resident at UPMC, conducted an H&P of a Medicare beneficiary with the initials B.K. Dr. Pommerening signed the electronic record for the H&P the next day. The medical record does not note that the attending surgeon, Dr.

Pedro Augusto Reck Dos Santos, met with patient B.K. prior to surgery on March 5, 2019. The consent form, however, is dated March 5, 2019, and bears a signature that, on information and belief, belongs to Dr. Dos Santos. Dr. Dos Santos signed the consent form at 7 pm on March 5, 2019, nearly two hours *before* the patient signed at 8:45 pm. Dr. Dos Santos falsely certified that he had "explained to the person signing above all of the information contained in this consent form."

Example 4: Bernadette Fedorka

117. On December 21, 2018, patient Bernadette Fedorka, a Medicare beneficiary, filed a malpractice suit in the Court of Common Pleas of Alleghany County, Pennsylvania, against UPMC, Dr. Luketich, and Dr. Sanchez, as well as other providers, for injuries she sustained – including end stage renal failure and respiratory failure requiring tracheostomy and ventilator support – during a lung transplant conducted by Dr. Sanchez.

118. Ms. Fedorka alleged numerous failures to adhere to the standard of care by Dr. Sanchez and the other Defendants. In addition, she alleged battery/lack of informed consent, stating in the Complaint:

> 208. Bernadette Fedorka never consented to the surgery performed by Sanchez.
> 209. Bernadette Fedorka was never properly informed about the surgery performed by Sanchez.
> 210. Sanchez committed battery on Bernadette Fedorka which caused all the injuries set forth herein.

Fedorka v. UPMC, et al., Complaint ¶¶ 208-210 (Ct. Comm. Pleas, Dec. 21 2018).

119. The Complaint further alleges, "At all times relevant hereto, Ms. Fedorka never authorized any third party, including her husband, to provide her written consent for surgery to UPMC and/or UPP (including lung transplant surgery) and she was not physically or mentally unable [sic] to provide such written consent herself." *Id.* ¶ 74.

120. Ms. Fedorka's account is consistent with Dr. Sanchez's practice of encountering the patient on the day of surgery in the operating room after the patient was unconscious under anesthesia. He did not meet Ms. Fedorka prior to the procedure to obtain her informed consent and could not obtain her consent once he arrived to perform the procedure.

121. In addition, Dr. Sanchez failed to properly obtain Ms. Fedorka's consent to participate in the Lung Bioengineering EVLP clinical trial. Ms. Zaldonis reported to an Institutional Review Board that Dr. Sanchez had not signed the consent form to participate in the study. Instead, a resident had signed. Dr. D'Cunha had also signed, but he wrote a note next to his signature to clarify that he had signed the form as the Principal Investigator of the research study and not the provider who had met with Ms. Fedorka to discuss the clinical study with her. Dr. D'Cunha took this unusual step to insulate himself from any negative repercussions of Dr. Sanchez's failure to obtain Ms. Fedorka's consent himself.

XIV. THE UNIVERSITY OF PITTSBURGH TERMINATED PLAINTIFF/RELATOR IN RETALIATION FOR HER REPORTING DR. SANCHEZ'S FAILURE TO OBTAIN INFORMED CONSENT FOR PARTICIPATION IN A CLINICAL TRIAL FOR A MEDICAL DEVICE.

122. The University of Pittsburgh fired Ms. Zaldonis after 36 years of service to the University and UPMC, because she reported an improper informed consent form to the Advarra Institutional Review Board ("IRB").

123. In her 29 years working on cardiothoracic transplants, Ms. Zaldonis received numerous promotions, rising up the ranks to become Lead Research Coordinator of Cardiothoracic Transplantation. During that time, she helped build UPMC's clinical research program in cardiothoracic transplantation into a leader in the country.

124. In October 2018, Dr. Sanchez approached Ms. Zaldonis in her office to ask if an informed consent form for participation in a clinical study had been executed in the Bernadette

Fedorka case. Dr. Sanchez explained to her that he wanted the document because Ms. Fedorka had brought a malpractice suit against him and the institution alleging that she had not provided informed consent for the procedure.

125. After looking through a binder of clinical study consent documents kept in her office, Ms. Zaldonis located Ms. Fedorka's consent form to participate in the Lung Bioengineering EVLP study. As referenced above in paragraph 121, Ms. Zaldonis noted that Dr. Sanchez had not signed the form. Instead, a resident had signed, in violation of law and UPMC policy.

126. Upon reviewing the consent document, Dr. Sanchez turned to Ms. Zaldonis and said, "You're not going to report this, are you?" Knowing that protocol required her to report the defective consent form to the Advarra IRB, Ms. Zaldonis responded, "I have to." Dr. Sanchez did not respond. He turned and walked out of Ms. Zaldonis' office.

127. A few weeks later, in November 2018, Stephanie Varholak, from the University of Pittsburgh human resources department, asked Ms. Zaldonis to participate in a meeting in the conference room located down the hall from Ms. Zaldonis' office. Upon arriving in the conference room, Ms. Zaldonis found Angela Gallagher, to whom Ms. Zaldonis reported, and Jean Bunyan, Executive Administrator in the Department of Cardiothoracic Surgery. Ms. Varholak, who led the meeting, informed Ms. Zaldonis that she was "under investigation" but did not tell her the subject of the investigation. Instead, Ms. Varholak, Ms. Bunyan, and Ms. Gallagher asked Ms. Zaldonis certain questions about a clinical study (the Novel Lung Trial: Normothermic Ex Vivo Lung Perfusion (EVLP) As An Assessment Of Extended/Marginal Donor Lungs). Ms. Zaldonis was confused by these questions, which were followed by additional questions provided in writing.

128. On January 8, 2019, Jean Bunyan came to Ms. Zaldonis' office and asked her to attend a meeting in the same conference room as the one used in November. Stephanie Varholak

was also present and ran the meeting. Ms. Varholak informed Ms. Zaldonis that the University of Pittsburgh had completed its investigation and concluded that Ms. Zaldonis had provided "inaccurate data." As a result, Ms. Zaldonis would be terminated. Ms. Zaldonis asked what "inaccurate data" she had supposedly provided, but Ms. Varholak and Ms. Bunyan refused to divulge any additional information, leaving Ms. Zaldonis completely in the dark and unable to defend herself.

129. The meeting ended with Ms. Varholak handing Ms. Zaldonis a termination letter that vaguely referenced "unprofessional communication" and "inaccurate data." Then, Ms. Varholak and Ms. Bunyan led Ms. Zaldonis to her office and instructed her to gather her personal effects into empty boxes. Ms. Varholak and Ms. Bunyan watched Ms. Zaldonis pack the boxes with photos and certificates – ordering her not to touch her computer – before they unceremoniously escorted her from the building after 36 years of service.

130. When Ms. Zaldonis told Dr. Sanchez that she would report his failure to properly obtain Ms. Fedorka's consent to the IRB, she engaged in protected conduct. She also engaged in protected conduct when she made her report to the IRB, because she made the report to comply with protocol and to properly inform the IRB so that it could execute its oversight role. She made the report knowing that it could play a role in producing negative consequences for the study and Dr. Sanchez and that her reporting could have reasonably led to a viable claim under the False Claims Act, 31 U.S.C. § 3729, *et seq*.

Count I: Knowingly Presenting False Claims
(31 U.S.C. § 3729(a)(1)(A), UPMC & UPP)

131. Plaintiff/Relator re-alleges and incorporates the allegations in paragraphs 1 through 130.

132. This is a claim for treble damages, civil penalties, reasonable attorneys' fees, and costs, under the Federal False Claims Act, 31 U.S.C. § 3729, *et seq.*

133. Between October 1, 2013 and the present, Defendants UPMC and UPP knowingly presented or caused to be presented false or fraudulent claims for payment or approval to officers, employees, or agents of the United States, in violation of 31 U.S.C. § 3729(a)(1)(A). The United States, unaware of the falsity of the claims made, and in reliance on the accuracy thereof, paid for claims that would otherwise not have been allowed.

134. By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

Count II: False Records or Statements
(31 U.S.C. § 3729(a)(1)(B), UPMC & UPP)

135. Plaintiff/Relator re-alleges and incorporates the allegations in paragraphs 1 through 130.

136. This is a claim for treble damages, civil penalties, reasonable attorneys' fees, and costs, under the Federal False Claims Act, 31 U.S.C. § 3729, *et seq.*

137. Between October 1, 2013 and the present, Defendants UPMC and UPP knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims made to officers, employees, or agents of the United States, in violation of 31 U.S.C. § 3729(a)(1)(B). The United States, unaware of the falsity of the claims made, and in reliance on the accuracy thereof, paid for claims that would otherwise not have been allowed.

138. By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

Count III: Retaliation
(31 U.S.C. § 3730(h), University of Pittsburgh)

139. Plaintiff/Relator re-alleges and incorporates the allegations in paragraphs 1 through 130.

140. This is a claim for two times the amount of back pay, interest on the back pay, loss of benefits, litigation costs and reasonable attorneys' fees under the retaliation provisions of the False Claims Act, 31 U.S.C. § 3730(h).

141. The University of Pittsburgh discharged Plaintiff/Relator and discriminated against Plaintiff/Relator in the terms and conditions of her employment because of lawful acts done by Plaintiff/Relator in furtherance of an action under the False Claims Act (31 U.S.C. § 3729, *et seq.*) and other efforts to stop one or more violations of the False Claims Act (31 U.S.C. § 3729, *et seq.*).

142. As a direct result of the University of Pittsburgh retaliation against Plaintiff/Relator for protected activity, Plaintiff/Relator sustained damages, including but not limited to loss of earnings and benefits.

Count IV: Wrongful Termination – Violation of Pennsylvania Public Policy
(University of Pittsburgh)

143. Plaintiff/Relator re-alleges and incorporates the allegations in paragraphs 1 through 130.

144. The University of Pittsburgh, through its agents, servants, and employees, terminated Plaintiff/Relator's employment in retaliation for her attempt to directly and clearly protect public safety by reporting to an Institutional Review Board a failure to obtain consent properly to participate in a clinical trial for a medical device. In doing so, the University of Pittsburgh violated the well-established clear mandate of public policy of Pennsylvania that

prohibits employers from discharging an employee for her refusal to partake in the employer's unlawful actions or for her decision to report those unlawful actions to the proper authorities.

145. As a direct result of her unlawful termination, Plaintiff/Relator has sustained a loss of earnings and benefits, emotional distress, and loss of future earning potential.

PRAYER FOR RELIEF

Plaintiff/Relator respectfully requests this Honorable Court to enter judgment against Defendants UPMC and UPP and grant relief as follows:

(A) The amount of the United States' damages, trebled as required by law;

(B) Such civil penalties as are required by law;

(C) A relator award in the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) or any other applicable provision of law;

(D) All costs of this action, including reasonable attorney's fees;

(E) Further relief that may be just and proper.

Plaintiff/Relator further respectfully requests this Honorable Court to enter judgment against Defendant University of Pittsburgh and grant relief as follows:

(A) Reinstatement of Plaintiff/Relator to her previous position with accumulated seniority, fringe benefits and all other rights;

(B) Full value of double the wages that she would have received had it not been for Defendant's illegal treatment, with interest from the date of the termination, in addition to reimbursement for lost pension, social security, experience, training opportunities and other benefits;

(C) Compensation for loss of future earnings and benefits;

(D) Enjoining of further retaliation against Plaintiff/Relator;

(E) All costs of this action, including reasonable attorney's fees;

(F) Further relief that may be just and proper.

JURY TRIAL DEMANDED

Plaintiff demands that this matter be tried before a jury.

/s/Michael E. Hoover
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CERTIFICATE OF SERVICE

On this 24th day of September, 2019, Plaintiff/Relator, through her counsel, hereby certifies that in compliance with Rule 4 of the Federal Rules of Civil Procedure, service of this *Qui Tam* Complaint will be made by first class mail on:

The Honorable William P. Barr
United States Attorney General
United States Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530-0001

Scott W. Brady, U.S. Attorney
Attn: AUSA Adam Fischer
United States Attorney's Office
Western District of Pennsylvania
United States Courthouse
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